K002019

MAR 3 0 2001

Summary of Safety and Effectiveness

DATE PREPARED

October 3, 2000

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

California Medical Laboratories, Inc. devices are substantially equivalent to the cited predicate device. California Medical Laboratories, Inc. devices have substantially equivalent intended uses as the cited predicate device. California Medical Laboratories, Inc. devices have technologic characteristics including material, dimensional and performance characteristics, which are substantially equivalent to the cited predicate device.

COMPANY AND CONTACT PERSON

California Medical Laboratories Inc.
1570 Sunland Lane
Costa Mesa, California 92626
714-556-7365
714-556-7997 (fax)
Michael Webb
General Manager, Operations

DEVICE NAME

California Medical Laboratories Inc. Retrograde Cardioplegia Cannula, Self-Inflating with either Guidewire Stylet or Malleable Stylet

COMMON NAME

Retrograde Cardioplegia Cannula

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

The claim of substantial equivalence is based upon the following device:

- Baxter RMI Retroplegia ® Cannula

DESCRIPTION OF DEVICE

The Retrograde Cardioplegia Cannula, Self-Inflating consists of a cannula made of a flexible PVC tubing consisting of one large lumen for infusion of cardioplegia solution and inflation of the balloon. A second smaller lumen is intended for pressure monitoring. A self-inflating low pressure PVC balloon is mounted on the cannula shaft proximal to the infusion holes, to maintain cannula position when the balloon is inflated. Balloon inflation is achieved by the differential pressure created inside the cannula during the infusion of cardioplegia solution. The balloon will deflate when infusion is stopped. The cannula is provided with either a guidewire or malleable stylet.

STATEMENT OF INTENDED USE

The Retrograde Cardioplegia Cannula, Self-Inflating is intended for use in the infusion of blood or cardioplegia solution into the coronary venous system, intraoperatively.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Baxter RMI Retroplegia Cannula is intended for use in delivery of blood or cardioplegic solution intraoperatively.

STATEMENT OF COMPARISON OF TECHNOLOGIC CHARACTERISTICS BETWEEN DEVICE AND PREDICATE DEVICE

California Medical Laboratories, Inc devices have technologic characteristics including material, dimensional and performance characteristics, which are substantially equivalent to the predicate device. Performance characteristics evaluated included the effects on hemolysis, leak/burst & pull testing, as well as, performance flow. Each of the results observed following such evaluations concluded that California Medical Laboratories device performed substantially equivalent even outperforming in certain aspects of the leak/burst and pull testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 3 0 2001

CalMed Laboratories
c/o Mr. Michael Webb
General Manager, Operations
California Medical Laboratories, Inc.
1570 Sunland Lane
Costa Mesa, CA 92626

Re: K002019
Trade Name: Retrograde Cardioplegia Cannula, Self-Inflating with either Guidewire Stylet or Malleble Stylet
Regulatory Class: II (two)
Product Code: DWF
Dated: March 22, 2001
Received: March 26, 2001

Dear Mr. Webb:

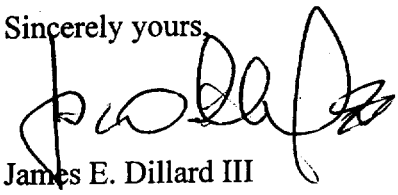
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002019

Device Name: California Medical Laboratories Inc. Retrograde Cardioplegia Cannula, Self-Inflating, with Malleable or Guidewire Stylet

Indications For Use: The Retrograde Cardioplegia Cannula, Self-Inflating is indicated for the infusion of blood or cardioplegia solution into the coronary venous system, intraoperatively.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002019

Prescription Use Y **OR** **Over-The-Counter Use** _____ **Per 21 CFR 801.109**